EXHIBIT 2

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	MDL No. 2804
	)	Case No. 1:17-MD-2804
THIS DOCUMENT RELATES TO ALL CASES	)	Hon. Dan A. Polster

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Monday, May 13, 2019

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HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

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Videotaped Deposition of JAMES E. RAFALSKI, held at Weitz & Luxenburg PC, 3011 West Grand Avenue, Suite 2150, Detroit, Michigan, commencing at 9:20 a.m., on the above date, before Michael E. Miller, Fellow of the Academy of Professional Reporters, Registered Diplomate Reporter, Certified Realtime Reporter and Notary Public.

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GOLKOW LITIGATION SERVICES
877.370.3377 ph | fax 917.591.5672
deps@golkow.com

Q. Have you ever served as an expert witness on a consulting basis before?

A. No, sir, I have never served as an expert in the capacity of a consultant.

Q. Okay. Have you ever written any articles that were published?

A. No, sir.

Q. Have you ever written anything of any kind that was published?

A. As a police officer, I wrote an article at the request of the Detroit News. It was in regards to the effectiveness of the DARE program.

Q. Okay. So you wrote something for the Detroit -- is it the Detroit News?

A. Detroit News, it's the publication.

Q. Did that used to be the Detroit Free Press or is that a different paper?

A. Different paper. Still two papers in Detroit.

Q. Okay. Was that like an op-ed, like an editorial kind of thing?

A. Sure. They published two, I guess, opinions, a pro and a con opinion.

Mine was the pro opinion of DARE, and there was a side-by-side con opinion of the effectiveness of that program.

Q. Okay. So you wrote that. Is there anything else you've ever written that's been published?

A. Not that I'm aware of, not that I gave any authorization for, no, sir.

Q. Okay. Have you -- and this is pretty obvious, but you're not an attorney; is that correct?

A. Not an attorney, no, sir.

Q. So in giving your opinions today, you're not trying to give legal opinions; is that right?

A. Well, the opinion I'm trying to give is based on my training and experience and my knowledge of the law and the regulations that are required to be adhered to by the companies. I'm not publishing a legal opinion as an attorney.

Q. Well, what I'm asking you is whether you -- are you offering today or in your report a legal -- a legal conclusion?

A. I think, yes, I am.

Q. Okay. Let me ask you a little about the work you've done in connection with this report.

First of all, the report is 180 pages, I believe.

A. It is, sir.

Q. Did you write it?

A. Yes, sir.

Q. Okay. You wrote it yourself or did you write it with help?

A. I wrote it with help.

Q. Okay. How much time did you spend preparing your report?

A. Well, I didn't keep track if you're going to ask me the exact hours, but I would say a considerable amount of time. It pretty much consumed me.

Q. When did you start working on the report?

A. Well, probably in the fall of 2018, I started having discussions about the type of documents and records that I would need, some of the topics in potential depositions, questions I would need to answer. So I started to give the framework

So within those families, there's -- my experience in doing these cases is there's generally a hierarchy of drugs where some drugs are ordered more often than others. They're just generally prescribed more.

So during the course of when a potential diversion would occur, there could be one strength of drug which actually occurred -- which really impacted what happened in America -- the oxycodone 30 product became a highly abused product. So companies should or would want to monitor within that drug family if there was a change in pattern where one drug started to get ordered in a much greater amount than the other drugs.

Along those same lines, another pattern is how companies order drugs. Typically in the old days they used DEA Form 222s. That's a paper form with ten lines. Some companies generally order drugs in the same manner.

I've reviewed countless number of forms, and as you go through the forms day

by day, you'll see patterns on how drugs are ordered, certain groups together. In the cases I've worked, when that pattern changes, so an easy one would be all of a sudden you see an order form with ten lines and all ten lines have oxycodone 30. If a company would start to change a pattern of orders like that, that would be an easy one.

Q. Is it also possible that patterns or size or frequency can change suddenly based on changed circumstances in a particular community?

A. Sure, anything is possible.

Q. Well, I don't just mean anything is possible. I mean, yes, anything is possible, but I'd like to be a little more specific.

A. Okay.

Q. Let's say -- let's say a hospital opens up in an area. Would that change patterns and could it change ordering patterns and size of orders and frequency of orders?

A. Well, I think that obviously has a possibility to cause some change. I'm

not sure that it would change the pattern. It may change the amounts or the types. So another -- as was one of my examples, the types could change.

Anytime a business model changes or a new contract -- a better example, if I could give you a better example.

Q. Sure.

A. Is a pharmacy could enter into a contract with a long-term care facility, and if they didn't provide guidance or information to their distributor, they could just start ordering a controlled substance that would be out of the norm of something they ever ordered before.

That's kind of the essence of the suspicious order system because you would hope the system would trigger to stop that order. Then it requires some due diligence where a company would actually call and they would learn about that contract. And then subsequent to that, the distributor or the person making the sale would probably confirm that that actual contract occurred and that

business relationship occurred.

So...

Q. So patterns can change?

A. Sure.

Q. Size can -- you know, unusual size can change. Frequency can change depending on the circumstances that occur in a particular community, right?

A. I've learned in my experience that the ordering and distribution of drugs is not static. It's heavily patterned, especially the more the customers, the more the established pattern, sizes and frequency. But new drugs could be introduced.

There's a lot of reasons why it could change. And that's not a bad thing, but those are the things that would trigger your system to stop an order and then you to evaluate it to make sure that -- not you personally, but so that it's evaluated, and then there's no chance of diversion.

Q. So while that investigation is going on, you're saying that those drugs should not be shipped to a place where let's say there's a new -- a new long-term facility

Do you agree with that statement that Mr. Rannazzisi made?

MR. FULLER: Form, outside of his scope.

A. Can you read it one more time for me?

BY MR. NICHOLAS:

Q. Yes.

DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion.

A. Well, based on my work on this matter and my review of records and systems, which I didn't have any previous knowledge of previous to when I did that, I would probably disagree with that statement by Mr. Rannazzisi, in looking at the historic failures by the companies to be in compliance with the suspicious order situation -- or regulation and just a general broad maintenance of effective controls to prevent diversion.

MR. NICHOLAS: It's been -- well, let's take a short break. We'll

go another 45 minutes after that and have lunch, if that's okay.

THE VIDEOGRAPHER: Going off the record, 11:34 a.m.

(Recess taken, 11:34 a.m. to 11:45 a.m.)

THE VIDEOGRAPHER: We're back on the record at 11:45 a.m.

BY MR. NICHOLAS:

Q. The DEA requires the retention of records to be for at least two years; is that correct?

MR. FULLER: Form.

BY MR. NICHOLAS:

Q. By policy?

A. Well, by regulation --

Q. By regulation.

A. -- the requirement is -- and that two-year applies to required records. So within the CFR, there are certain records, examples would be biannual inventories, order forms. Any of the records that are in the records section of the CFR have a two-year retention.

And there's a carve-out that if

a state has a longer retention period, that the registrant could be subjected to that, but that two years only applies to those certain records that are cited in the CFR.

Q. So -- but the carveout that you're talking about doesn't apply to suspicious order reports, right? That's within the two -- that's subject to the two-year regulation?

MR. FULLER: Form.

A. No. The suspicious order reports aren't part of the two-year retention.

BY MR. NICHOLAS:

Q. They don't have to be retained at all?

A. Well, under my opinion, it would be they would be retained forever.

Q. Right, but, I mean, the regulation doesn't require -- I understand that might be your opinion, but is there any regulation that says they have to be retained for any length of time?

A. I would say the maintenance of effective controls to prevent diversion would

be applicable to say that they should retain the suspicious order reports or any due diligence related to them.

Q. There are specific sections -- there are specific regulations that address records retention, correct?

A. Yes, sir.

Q. And those --

MR. FULLER: Form.

BY MR. NICHOLAS:

Q. -- regulations identify the categories of records that have to be kept and for how long, correct?

MR. FULLER: Form.

A. The CFR does address that, but those are the required records. For example, there are some records that registrants keep in the course of their business that aren't a required record. So just so we're on the same understanding as to -- the two-year retention is only under those required records; dispensing records for a dispensing doctor, two-year retention; biannual inventories, order forms, those are all part of the required records.

BY MR. NICHOLAS:

Q. So the things we're talking about now, suspicious order reports or due diligence documents, are not part of the kinds of records that are required to be retained under the CFR and the regulations?

A. Well --

Q. That's a yes or a no.

MR. FULLER: Object to form. He's already testified they were.

MR. NICHOLAS: That's not what he said.

Go ahead.

THE WITNESS: So could you restate the question? I'm sorry.

BY MR. NICHOLAS:

Q. Does the CFR or its regulations require in writing and as identified suspicious order reports?

MR. FULLER: Form.

MR. NICHOLAS: I'll ask it again. It was a crappy question.

BY MR. NICHOLAS:

Q. Does the CFR identify suspicious order reports as among the

documents that have to be retained for at least two years?

A. I would say yes, under the maintenance of effective controls, but I think there's not a lot of clarity on whether that is essentially a required record.

Q. Does the CFR identify due diligence documents as documents that are required to be retained for at least two years?

A. I'm going to respond the same: Under maintenance of effective controls, I think that requirement requires the retention of due diligence records. The CFR doesn't speak specifically to a due diligence record, but that would be a record that would be maintained within the requirement of that regulation.

Q. For at least two years?

A. Again, my opinion, they should be kept permanently.

Q. No, I'm not asking about your opinion. I'm asking under -- what the requirement is under the law as you understand it.

A. Under the regulation as I understand it --

Q. Yeah.

A. -- it doesn't speak specifically to due diligence records. So I -- a two-year retention -- if a registrant was to review the CFR, there's no mention of a due diligence record, so I would say it's not two years.

But again, I'd just restate that I would see no reason why they wouldn't retain them indefinitely.

Q. Okay. I just want to go back for one second to when you said several times that -- you talked about your understanding about how the DEA -- or your belief that the DEA does not -- has never given approvals of suspicious order monitoring systems, and you said that the manual said you're not supposed to and all that.

When did you start at the DEA?

A. 2004.

Q. Okay. When you refer to the manuals, to the Diversion Control Manual, you were referring to a manual that you read in

communication on page 32 of my report.
BY MR. NICHOLAS:
Q. Okay. Hold up. Yeah.
I just want to know -- I mean, all I really wanted to know is did you put in your report that Mr. Gitchel said in 1984 that the DEA doesn't approve --
A. No, I think I may have misspoke. I think it was in regards to stopping shipments of --
Q. Okay.
A. -- orders.
Q. Okay. All right. That's fine.
A. That's why I wanted to review my report, to make sure.
Q. This was an instance where you reviewed your report and found something -- and found something that I agree -- supported my point, so that's good. I should let you review your report more often.
A. Yeah, you tried to stop me. But I just want to be factually correct. It's an important subject.
Q. I appreciate it.
A. And I had a recollection that

that was discussed, but it was about stopping an order, so...

Q. All right. So since we are talking about sort of what -- since you just sort of brought up the shipping requirement.

A. Yes, sir.

Q. First of all, just so the -- so we've got it on the record, what do you understand -- it's a weird word, because it's a shipping requirement, but it really -- it's a reference to not shipping.

So can you just explain what the shipping requirement is to your understanding?

A. Well, first, I've never -- there's never really been a formal term. A shipping requirement, I don't know if that's an industry term or just somehow got created, but it never was referred to as just a shipping requirement.

I mean, it's -- it's the mere fact that when a company uses a suspicious order system and identifies a suspicious order, they don't ship that order until they dispel the suspicion about it and whether or

not it's going to be diverted to ensure that gets properly distributed.

Q. Okay. So let me ask a couple of basic questions here.

Does the CFR or the regulations related to the CFR on this subject say anywhere that there is a requirement that distributors not ship suspicious orders?

A. I think they give guidance to distributors under the maintenance of effective controls. Only saying that because if a distributor discovers a suspicious order, to ship it without dispelling the suspicion, that kind of violates the maintenance of effective controls.

So I don't want to say it's just a commonsense interpretation, but to identify something suspicious that is suspicious of diversion and then just shipping it without stopping it and dispelling it, that's at the core of that regulation.

Q. Does the --

A. And the law.

Q. Does the regulation say

anything about ship -- does the regulation in words, words, say anything about shipping?

A. No, in words, the regulation does -- and just the --

Q. It does or does not?

A. It does not say the word "shipping."

Q. Okay.

A. But again, I go back to the maintenance of effective controls, and secondly, it's been since the day I started at DEA, that's been the interpretation of the DEA, and I think there's been several communications, Mr. Rannazzisi's letters.

Q. Okay.

A. All the way back -- now I can go back to Mr. Gitchel's letter in 1984, about stopping an order because that was the topic that I discussed -- that I confused on your earlier question.

Q. Do you -- is it your testimony that the decision as to whether to ship or not to ship an order that's been reported to the DEA is left to the discretion of the distributor?

A. So I think the discretion on whether to ship or not ship is solely the decision of the distributor. The DEA doesn't inform a distributor if or when to ship an order or not to ship an order. So the answer to that would be yes.

Q. And if a distributor asks the DEA -- if the distributor came to the DEA and said, we've got this order, we have questions about it, should we ship it or not ship it, the DEA won't answer that question?

A. So I'm not sure that I'm comfortable speaking for the entire DEA, but how I'd like respond to that is through my experience and what has occurred in the past.

So there may be a time when you receive a call from a registrant that may ask a question like that or a similar question, so generally, you can -- first, I would always state there's two -- two situations, and we're just going to talk about suspicious orders -- or, I mean, about distributions.

And first, I'll always state that I can't tell a distributor when to ship or not to ship, but I may ask a lot of

Q. Okay. And so when you refer to flagged orders, you've got -- you know, your top column, it's a grid.

A. Yep.

Q. And from left to right, across the top, first it's the name of the distributor. Then it says: Flagged orders of oxycodone (dosage units). Then it says: Flagged orders of hydrocodone (dosage units).

Let's just take AmerisourceBergen, since this is the first one.

A. Okay.

Q. Okay. Go down to orders of oxycodone (dosage units), and then it says the number, which is 50,578,040.

What's that a number of, dosage units?

A. Yes.

Q. Okay. And then what does the 86% of total dosage units mean? What is that -- 86.5% of what?

A. Of the amount that was distributed during the time period stated above into the CT1 jurisdiction.

Q. Okay. And then moving across to the 24th -- to the flagged orders of hydrocodone dosage units, it's 24,412,050, which represents 92.7% of the total dosage units, correct?

A. Yes, sir.

Q. So are you saying -- well, what are you saying when you express this? I shouldn't say.

I mean, you're showing it. What does it mean?

A. So the methodologies applied to the distribution, once the suspicious order is identified, the criteria I used is if there was no due diligence to dispel the suspicious order or it wasn't reported, then every subsequent distribution would be a suspicious order.

Q. Let me -- I hate this expression, but I'm going to have to unpack that.

So the criteria you used -- you say once the suspicious order is identified?

A. By the company -- or by the methodology, I'm sorry.

Q. I mean, that's my first source of confusion is, are these suspicious orders or are these what you are suggesting should have been suspicious orders, that you're basing this on?

A. Well, it's not suspicious --

MR. FULLER: Objection to form.

A. It's not suspicious orders. It's dosage amounts that resulted from suspicious orders. So the methodology -- my understanding of what Mr. McCann did -- and I don't want to speak for him.

BY MR. NICHOLAS:

Q. Okay.

A. -- is he looks at the distribution, the ARCOS data for the distribution for AmerisourceBergen drug company, he applies the methodology, and if there are no suspicious orders, it just runs along the distribution.

At some point, if there's a month that exceeds the greatest month in the previous six-month, that stops and it's a suspicious order. So at that point, if there was a due diligence to dispel that suspicious

order, if I could find that in my investigation, then it would continue on.

If there was no due diligence and, as my report details, there wasn't during the early time periods -- during most of the time period there was no due diligence to dispel suspicious orders, so every subsequent order would become a suspicious order.

Q. On what basis are you saying that there was no due diligence done to -- with regard to flagged orders? What is your basis for saying that?

A. There were review of records submitted on discovery.

Q. Records for --

A. Now, let me -- can I correct this?

Q. Yeah.

A. I don't want to say none whatsoever. I believe that probably there may have been some individual instances of due diligence, but in a general statement, at a systematic level, there was insufficient due diligence. Or none.

Q. And what is your basis for that statement?

A. Reviewing records.

Q. Reviewing records provided to you by the plaintiffs?

A. By the drug companies under discovery.

Q. You only had access to the records that the drug companies supplied in discovery to the extent they were sent to you by the plaintiffs' lawyers that were retaining you, correct?

MR. FULLER: Object to form.

A. I'm not sure how to answer that because I guess I hope I got all the records.

Now, I'm not indicating that I looked at every one, but I looked at enough to draw a conclusion or an opinion that there was insufficient due diligence.

BY MR. NICHOLAS:

Q. Well, if you weren't sent records that are -- that exist, how do you know how many of the -- how many -- how do you know whether you looked at a few, some, most or all of the records? How do you know?

A. I think that's kind of a hypothetical question.

Q. No, it's not hypothetical. You told me that -- you told me that you obtained records from plaintiffs' counsel, correct?

A. And it's my belief that I had access to all the records. Now, there's no way that I would know if that occurred or not. That's -- I'm hopeful, as their expert opinion, that I had access to all of the records.

I can't affirmatively say that they gave me every record. I -- that's why it's kind of a hypothetical.

Q. Well, right now it is a hypothetical because we really have no idea what records you were provided, what records you were provided and what you weren't because I think you told us that you didn't write down all the records that were provided to you.

A. Well, I would say that in regards to this matter, I reviewed sufficient due diligence records to draw -- to make my opinion.

Q. Now, sticking with that for a minute, just because you did not review due diligence records from 2010, 2011, 2012 -- let's assume you didn't see due diligence records or as many as you would have liked. That doesn't mean that the due diligence wasn't done, does it?

A. Well, as far as the DEA is concerned, if there's no documentation or record of it, a due diligence file, my opinion would be based on that that doesn't exist.

Q. Well, we've already discussed the fact that there was no requirement in the regulations as to the retention of due diligence records --

MR. FULLER: Object to form.

BY MR. NICHOLAS:

Q. -- for any period of time, right?

MR. FULLER: Object to form.

That's not the witness's testimony.

A. So I don't think that's exactly what my statement was. I think my statement was is that it wasn't contained as a required

record in the recordkeeping section of the CFR.

BY MR. NICHOLAS:

Q. Yeah.

A. But it was of my opinion that it's covered under the maintenance of effective controls, and it would be my opinion as -- with my experience and my training and my knowledge, is that it should be kept forever. It's a historical record, and it should be kept by the registrant much greater than two years.

Q. Now, you keep saying that the requirement to maintain records is contained in the section pertaining to maintenance of effective controls, but just so the record is clear, there's nothing in the section on the maintenance of effective controls that makes any reference to records, correct?

A. Well, I --

MR. FULLER: Form.

A. I think within the statements, that's what that statement means.

BY MR. NICHOLAS:

Q. Means. But I'm asking whether

you go right down each company, all right. You've got one, two, three, four, five companies, and in the case of each one, you've got a parenthetical that says that somewhere between -- that identifies somewhere between 86.5% and 95.3% of total dosage units, okay?

A. Yes, sir.

Q. All right. And that means what? Is that the number of dosage units that in your opinion should not have been shipped?

A. Well, in my report, if we -- I actually make a statement in regards to that on page 46.

Q. Okay.

A. So it starts after the footnote 151: However, it is my opinion to a reasonable degree of professional certainty that applying the tests set forth in the Masters Inc. and Drug Enforcement Administration provides a reasonable estimate and initial trigger on a first step to identifying orders of unusual size.

Q. So are you saying that --

A. Well --

Q. -- this is the number of --

MR. FULLER: Well, go ahead and finish your answer.

MR. NICHOLAS: Okay. I thought you were done. Sorry.

A. So -- and I can read the rest of the paragraph.

BY MR. NICHOLAS:

Q. Don't read. I'd rather you just tell me just in words, in your words, what -- you know, what is it you're trying to convey here?

Are you trying -- are you trying to say, or are you saying that in your opinion, 86.5% of the total dosage units for Ameri- -- you know, under the AmerisourceBergen drug thing, are dosage units that should have been reported as suspicious orders?

A. I'm saying based on my experience and my opinion, based on some documents that when a suspicious order occurs as a result of the methodology and there's no action taken, no due diligence action taken

to dispel that suspicious order, that all the -- all the orders from that point forward, I'm considering them to be, you know, the result of suspicious orders.

Now, that --

Q. Okay. All right. So my question is -- all right. So let me try this.

Are you suggesting in your report that more orders should have been reported as suspicious?

A. Well, I don't think it suggests that. I'll restate it again.

So when the system triggers a suspicious order, it doesn't reset to the next order to be a suspicious order. So how I interpret the regulations and how my training is and how the Masters ruling and some of the documents I've read in regards from McKesson and Cardinal and Prevoznik's deposition testimony, is that once a suspicious order is identified by registrant, it should be stopped and there should be a due diligence to dispel whether or not that suspicious order is in fact suspicious.

If the registrant takes no action and just continues to ship subsequent orders in that order, then they're all suspicious orders.

Now, my last paragraph kind of sums up that this is how I applied this, and, you know, it's in regards to how the court would or would not accept it and there would be other methodologies. So that's how I interpret it.

Q. You know, on this subject I think -- well, are you able to tell us -- are you able to -- well, let's see.

Let's say an order is identified by a distributor as suspicious, okay?

A. Yes, sir.

Q. And it's reported to the DEA as suspicious.

A. Yes, sir.

Q. Okay. You agree that that doesn't necessarily mean that that order -- that the pills associated with that order are going to be diverted, right?

A. No, I think that's exactly what

it means.

Q. You think every time that an order is reported as suspicious that those pills turn out to be diverted?

A. I don't know that I could draw that conclusion, but I --

Q. That's the conclusion I'm asking you about.

A. Well, I wouldn't draw that conclusion. The only conclusion I would draw is that if a registrant is adhering to the law and the regulations and has a suspicious order system in place and their system identifies that, I would hope that they believe that they're reporting to the DEA what they believe to be a suspicious order.

Q. I'm asking you a completely different question, okay?

My question to you is: When an order was reported as suspicious -- strike that. Strike that, because I -- I asked a confusing question.

I think what you're saying is that there are -- but tell me if I'm wrong -- is that more orders should have been reported

as suspicious than were reported; is that right?

A. No.

Q. Okay. So you think that the appropriate number of orders --

A. I --

Q. -- into Track 1 and Track 2 jurisdictions that were reported as suspicious was indeed appropriate, that the right number was reported?

A. This methodology doesn't look at it that way because there was no due diligence so --

Q. Hold on. Let me stop you there.

MR. FULLER: Well, object --

MR. NICHOLAS: Go ahead. No, I'm sorry. You're right. You're right. Go ahead.

A. Because there was no due diligence. So the methodology is not applied to identify future orders that are suspicious, because when you don't dispel the suspicion or the potential that it's going to be diverted and you can clear it to say that

it's not going to be diverted, then every subsequent order, in my -- in the way I've applied this, would be a suspicious order based on the policies and the guidance and my experience with the DEA.

BY MR. NICHOLAS:

Q. So your entire analysis here rests on the premise that no due diligence was done on the orders that you're reporting on here; is that right?

MR. FULLER: Object to form, misstates his prior testimony.

A. No -- either no or insufficient due diligence.

BY MR. NICHOLAS:

Q. Okay. So there was either no due diligence or insufficient due diligence on, in the case of AmerisourceBergen, 50,578,040 dosage units. That's what you're suggesting?

A. Just so that I'm clear so we understand each other, that represents total dosage units and it's not orders. But, so at some point, if there was an effective due diligence, then I believe the methodology

would start monitoring it again until the next instance where there would be a suspicious order, and then that would require due diligence whether or not to clear that.

So it's -- you know, the critical thing I think that we -- that, you know, that we are having trouble communicating --

Q. We're definitely not communicating right now and I'm sure I'm not understanding this.

A. -- back and forth is the concept that when you don't do due diligence, that that makes every subsequent order a suspicious order.

Now --

Q. That's what you're saying?

A. Yes, if there is insufficient or there's incomplete or there's no due diligence.

Now, that's a methodology that's, I think, up to the court whether or not to accept, but that's -- so it's just as long as you understand clearly on how I had this methodology applied.

Q. So again, your methodology rests on your --

A. Opinion.

Q. -- conclusion or opinion that either no due diligence was applied or insufficient due diligence was applied -- you know, was utilized by any of these companies, and that results in these large numbers of dosage units and these percentages; is that right?

A. Yes, sir. My -- I'd like to add to that as my final -- the final in the -- on again, on 46, and this will maybe be a clarification of what I said earlier, the last sentence of the first paragraph: I say this understanding that the litigation will be advanced by selecting a methodology qualifying a volume of pills that entered the CT1 jurisdictions unlawfully and providing this data to an economist to measure harm caused by this volume.

Q. Yeah. You say in the -- the first sentence of that paragraph says: I've been asked to identify the number of opioid pills that entered Cuyahoga and Summit

A. That's not what I respond -- how I answered the question just a couple of questions ago.

So there could have been at some point for each of these companies where they designed or developed a system where they met the regulatory and the legal requirements. They had due diligence. They had an effective system, and they began to identify suspicious orders, and they -- they did a -- more than a cursory approval and they did due diligence. So that would stop the count.

And then the methodology would be applied again, and every one that was identified, if there was effective due diligence, it wouldn't be counted as a distribution to the CT1.

Q. Did you stop the count at any point in this analysis?

A. No, sir.

Q. And that's because you assumed that there was no due diligence done at any point from 1996 to your end date here --

MR. FULLER: Object --

BY MR. NICHOLAS:

Q. -- at least for the purposes of your numbers?

MR. FULLER: Object to form.

A. It's not an assumption. It's based on my review of records and depositions and documents that I couldn't find a time period where I believed there was sufficient due diligence -- well, there was actually a complete failure.

There was the failure to stop suspicious orders, there was ineffective suspicious order systems, but in regards to what caused these large numbers, it was the failure to have the maintenance of effective controls to prevent diversion, which is the act of the due diligence, the reviewing those orders to approve them as was detailed in the Masters opinion.

BY MR. NICHOLAS:

Q. Okay. Now, see if we can agree on one thing here, which is this: There could be an order of unusual size or frequency or pattern that is shipped. Whether it should have been or shouldn't have

been, we can put aside for another day. Okay? Let's just say that there's an order of unusual size, frequency, pattern, that, in fact, was shipped and it -- you can even say -- and let's say it should have been reported as a suspicious order, but it shipped. All right?

Do you agree that even though that order was shipped and even though you say it shouldn't have been shipped, it doesn't necessarily mean that the pills that underlie that order are going to be diverted. You don't know.

MR. FULLER: Object to form.

BY MR. NICHOLAS:

Q. Correct?

A. So I'll answer that question by saying that if it's identified as suspicious order by unusual size or unusual frequency or deviating form -- you know, substantial deviation from a pattern, so to me that puts it as a probable, greater than 51% that it's going to be diverted because it's been identified.

So I can't draw the conclusion

that I don't know that it's going to be diverted. I probably can't draw a definitive statement that it is, but I'm going to say that it's more probable because the system identified it.

Q. So you got it at 51% above, it's going to be diverted; is that what you're telling me?

A. Well, that's the definition of probable. If it's an effective suspicious order system, I believe the percents would rise much higher than that, but I guess that depends on the effectiveness of the suspicious order system.

Q. Where are you getting that percent from? Where are you getting that from, just your own --

A. What?

Q. The 51, the probable, where are you getting that it's probable?

A. That's my belief of what probable means.

Q. Okay. Other than your belief, is it written down anywhere? Is there any research on that? Is there any data on that?

Is this just -- just your belief?

A. Not that I can cite.

Q. Okay.

MR. FULLER: Vegas odds.

MR. NICHOLAS: Okay.

BY MR. NICHOLAS:

Q. Did you look at any individual orders from any pharmacies in the Cuyahoga or Summit Counties?

A. I looked at some DEA 222 forms, but I believe my recollection, it was out of maybe the Boston area, so I would say no.

Q. Okay.

A. No original records. I reviewed no original records.

Q. You reviewed data that was in the aggregate, right, totals? Correct?

A. No. I reviewed -- so just so we're clear on, you know, what we're talking about, so there's no confusion.

Q. Uh-huh.

A. So to me, in the DEA world, an original record is the actual DEA order form, the invoice or a CSOS electronic order form. So that's what I would consider an original

record. Also provided to me, there's the ARCOS data, which is not an original record, and there were some electronic databases that appeared to me to be an electronic spreadsheet or an electronic format of orders that distributors or registrants had submitted as part of the discovery. But none of those would be what I would consider an original record.

Q. Can you identify a particular order from a particular pharmacy that you believe should have been reported as suspicious?

A. Well, in my assignment to create this and do the investigation to come to this opinion, there wasn't a requirement for me to actually find specific orders that were suspicious.

First of all, it would require the use of the suspicious order system of the registrant, like what would be the criteria. The -- and the thing I found in doing my opinion is that probably the most critical part of setting up a suspicious order system is the due diligence or sometimes in the

industry they call it the onboarding, and that's to establish what the criteria is. I said earlier what the usual is.

And I found it difficult because I didn't really find an adequate effort to set up what actually would be a usual or what would be an expected order. So for me to go in and try to make that kind of analysis wouldn't be possible.

Q. So sitting here today, you can't identify a particular order from a particular pharmacy that should have been reported as suspicious that wasn't; is that correct?

MR. FULLER: Form.

A. I don't know because I didn't task myself to do that.

BY MR. NICHOLAS:

Q. Sitting here today, can you do it? I know you didn't -- I know it wasn't part of your job description here. That's all I want to know is can you do it today? Is it part of your report?

A. Well, actually, let me retract. I think I did that and I think it's on

A. Well, I guess I'm going to not answer, not based -- well, based on his instruction, but it's because whether it's a fact that's known by -- discoverable by just the general public, and I -- I don't know, so that kind of makes me not want to answer that question because I don't know if a person could just do some query from the general public and obtain that answer.

Q. Well, I can tell you that this deposition is designated as a confidential process to which the public does not have access and will not have access.

So with that assurance, can you answer the question now as to whether -- the simple question of whether the DEA keeps suspicious order reports on a database?

MR. FULLER: No, Counsel, hold on one second. The Touhy request has no bearing on whether this is kept confidential or not. Touhy authorization says he can't testify to anything that is not publicly known and that he gained information during his employment. Touhy authorization

allows him to testify based on the facts reviewed and provided in this case. So I'm still going to give him the same instruction.

I'll be honest with you, I don't know if it's public knowledge or not, whether it's in a database or not. It may be.

MR. NICHOLAS: Okay.

BY MR. NICHOLAS:

Q. Do you agree with the statement made by Mr. Rannazzisi in his deposition that 99% of doctors prescribe opioids for legitimate medical purposes?

A. I don't really have an opinion or I really don't agree or disagree. I don't have sufficient knowledge or experience or reviewed any studies to be able to make a comment on that.

Q. And do you agree with the statement made by Mr. Patterson of the DEA, formerly of the DEA, testifying in front of Congress that 99.9% of doctors are trying to do the right thing?

A. My answer --

MR. FULLER: Form.

Go ahead.

A. My answer would be the same. I -- I don't know the pure math of that question, but with over 1 million doctors, 99.9%, I'm not sure --

BY MR. NICHOLAS:

Q. Do you think the vast majority of doctors are trying to do the right thing?

MR. FULLER: Form, scope.

MR. NICHOLAS: You can answer.

A. I would agree with that, that I have no experience or knowledge that says, you know, anything otherwise than the vast majority. I guess we could maybe dispute about what vast majority is, but...

BY MR. NICHOLAS:

Q. When do you believe the opioid crisis began?

A. I would probably say the onset would be the Internet pharmacy activity, the illicit Internet pharmacy activity, I think 1999, around in that time period.

Q. Okay. When did you first become aware that there was an opioid crisis?

Around that time?

A. No. Probably when I started my employment with the DEA in the academy.

Q. 2004?

A. Yes, sir.

Q. Is there a point at which you believe the opioid crisis became common knowledge?

A. Yes.

Q. When is that?

A. Well, could I get a clarification of what you believe is common knowledge? Because what's common knowledge to me is -- would you -- would your definition of that be just if you were to stop somebody and say what is an opioid?

Q. How about known to government entities, cities, towns, counties, states.

MR. FULLER: Form.

A. Well, I think it's -- I think it probably coincided with when the Internet pharmacy illicit conduct got to -- identified. There was a study that was being done and it was published and showed the conduct of these Internet pharmacies and

would consider to be overprescribing? Because there's a couple of different ways I think I could interpret that.

Q. Did doctors prescribe too many opioid -- well, strike that. I'll try it again.

A. Let me --

Q. Was there a period of time when -- or do you believe doctors prescribed more opioid pills than were medically necessary for their patients?

MR. FULLER: Object to form. He's not a medical doctor.

A. Well, my investigation into some of them that I detailed as at least bulleted in my report, would say that I would ask -- answer that affirmatively because I have some experience with doctors who did issue illicit or diverted prescriptions.

So, you know, just in a general answer would be yes. Now, I'm not going to qualify that with how many or what, but that's one of the essences of how diversion occurs.

///

BY MR. NICHOLAS:

Q. Are you able to tell -- well, you wrote on your report on page 46, and we read this already, that you had been asked to identify the number of opioid pills that entered Cuyahoga and Summit Counties unlawfully, and then you went on to say it's an impossible task, right? Page 46, first full paragraph.

A. Yes.

Q. Okay. Are you able to tell us the correct number of pills that should have been shipped into Cuyahoga and Summit Counties lawfully?

A. No, sir, I cannot provide that information -- or did I calculate that information or --

Q. Do you have any sense of it at all?

A. Well, I'm supportive of my opinion, and that's the failures by the registrants during the time period was a significant contribution to diversion and the amount of pills. But to put a calculated number, I can't do that. My methodology has

come to some conclusions based on, you know, the due diligence factors.

Q. And in some regards, you'd almost have to be a doctor to know an answer to a question like that, right?

MR. FULLER: Form.

A. Well, I think that would be one aspect, to be a doctor. But then, you know, there's a lot of other factors that also would be taken into consideration.

BY MR. NICHOLAS:

Q. But, I mean, you don't feel qualified to look at a prescription for a patient and know whether that prescription is appropriate or not, correct?

A. Well --

MR. FULLER: Same objection.

A. I don't want to be argumentative, but in my experience of doing some cases, there have been instances where I could look at a prescription, knowing how it was written or the procedure that it was used, and I could say that that was not a legitimate prescription.

One example would be in one of

the cases I worked, patients would meet doctors -- not patients. People would meet a doctor in a parking lot, pay a hundred dollars and get a prescription. So I don't know that I would have to be a doctor to be able to say that wasn't a legitimate prescription.

BY MR. NICHOLAS:

Q. Fair enough. Sounds like you're a little bit of a doctor, a little bit of a lawyer and a little bit of a witness.

A. I just think that that doesn't take either -- any of those quantifications to say that there's something wrong with that prescription.

Q. Okay. Just a little more, and then I'll be done.

Now, you attended DEA basic diversion investigator school in 2004; is that right?

A. Yes, sir.

Q. Was that training at Quantico?

A. Yes, sir, it was -- I don't want to say custodial training. It was a -- you actually stayed at the facility, 12-week

Q. Now, there are some customers, isn't it true, who are going to consistently order over these limits because they're large customers; isn't that right?

MR. FULLER: Object to form, vague.

A. Well, I guess that is a possibility. I didn't see anything that would not require an employee of Cardinal to follow this procedure that would exempt any type of customers or have them fail to take this appropriate -- or this -- not appropriate -- take this action as required.

BY MR. PYSER:

Q. What the policy says is on a daily basis, cage-involved personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations DEA should be notified if possible before the order is shipped and a copy of all such orders should be maintained in the division's suspicious order file, along with the regulatory agency contact form noting any

specific instructions from DEA.

Correct?

A. Yes, sir.

MR. FULLER: And I don't know what he's reading from, but if you want to pull the policy to make sure he's reading it accurately, you're welcome to do so. I don't know --

MR. PYSER: Counsel, we can drop the speaking objection. He's already answered.

MR. FULLER: No, I won't drop the speaking objections.

BY MR. PYSER:

Q. So let's take an example, the Cleveland Clinic. They're in Cleveland, Ohio. It's a large medical facility.

Would you expect the Cleveland Clinic to order, when they order from Cardinal Health, more than 800 capsules of hydrocodone at a time?

A. I don't really have an opinion either way. It's a possible reasonable assumption, but without seeing the distribution datas or the purchasing

requests, I don't know.

Q. And you haven't looked at that information. You haven't gotten to that level of granularity in your work?

MR. FULLER: Form.

A. I didn't review the Cleveland Clinic or the ingredient limit reports for specifically looking for the Cleveland Clinic. I focused on the retail or the pharmacies.

BY MR. PYSER:

Q. Do you believe that Cardinal Health should have stopped shipping hydrocodone and other pain medicine to the Cleveland Clinic based on the fact that there were times when the Cleveland Clinic ordered more than 800 tabs of hydrocodone at a time?

A. So how I'll answer that is that this policy was set up by Cardinal and it's in response to how Cardinal identified the scope of the businesses they supply.

So my opinion is based on the policy that Cardinal set up. I didn't set up this policy for them; they did. So if their policy requires them to take an act and

they've set the limit up at 800 tablets, then unless they modify their policy or they have some exception, I -- this is their policy, and this is what they're requiring their employees to do.

Q. Sir, do you think that it would be appropriate to deny cancer patients at the Cleveland Clinic medication based on this absolute limit? Yes or no?

MR. FULLER: Object to form.

That wasn't the same question.

A. Well, I think to answer that question, if that did occur because they had a defective suspicious order system, they should correct that so that doesn't occur.

But so -- I guess that's a hypothetical that I don't really want to comment on, but the main thing that I want to make sure is that -- on my statement is that this is Cardinal's policy, and this is what they're requiring their employees to do.

BY MR. PYSER:

Q. Sir, where do you get the opinion that there was no flexibility around this policy and Cardinal Health had no choice

specifically say it's something they did or didn't do. I would just give them in some matters guidance. It would be a guidance that -- because in most regulatory investigations, I may ask to see some due diligence on a specific customer, and sometimes it would come up when I asked for it that they -- the registrant would tell me that it's not a required record.

So the option was this is -- as part of a work plan or a regulatory investigation, a registrant wouldn't have to show me the due diligence. In that case, I'd have to subpoena.

BY MR. PYSER:

Q. You're one diversion investigator when you were working at DEA, correct?

A. Yes.

Q. Do you know one way or the other whether the diversion investigators who visited Cardinal Health's facilities ever told them about this indefinite record retention policy that you're putting forward in your expert report?

MR. FULLER: Objection. And remind you of your Touhy obligation. Anything that is internal policy at DEA or communicated while you were on the job is outside the scope of what you're authorized to testify to.

A. I'm not aware.

BY MR. PYSER:

Q. So on page 50 of your report, you have a chart that talks about suspicious orders reported in the CT1 jurisdictions, right?

A. Yes.

Q. Okay. And there's two columns, pre-shipment reporting and then -- on the left, and on the right, post-shipment reporting, right?

A. Right. Yes, sir.

Q. Okay. On the right side, the post-shipment reporting, it's blank until 2005, correct?

A. Yes, sir.

Q. And that's blank there because you know from testimony that Cardinal Health was submitting ingredient limit reports to

DEA, but we just no longer have those records; is that right?

A. Sir, I believe my report says that I could not find those -- I could not find -- those weren't provided to me and I did not find those reports.

Q. You also reviewed the testimony of Steve Reardon we talked about earlier today, and he said Cardinal Health was sending ingredient limit reports to the DEA beginning in the early '90s, correct?

A. I don't have a recollection of that exact statement in his deposition.

Q. Did you have any reason to believe Mr. Reardon wasn't telling the truth if that is, in fact, what he said?

A. No, I don't have any independent knowledge of not -- whether to believe him or not to believe him.

Q. So on page 50 we have blanks under post-shipment report, where it's unknown, but you filled in zeros on the left side for pre-shipment reports all the way from 1996 to 2012, correct?

A. Yes.

Q. We talked earlier about these agency contact forms for phone calls to DEA?

A. Yes, sir.

Q. Is it possible that at some point from 1996 through 2012 employees from Cardinal Health may have called DEA before shipping an order that was destined for Cuyahoga or Summit County?

A. If that occurred, I would have an expectation to see one of the agency contact forms.

Q. But knowing that we don't have any agency contact forms from Wheeling, West Virginia, is it possible that people spoke on the phone, but today, from 1996, it's 23 years later, so 23 years later, is it possible a phone call was made but we don't have a record of it?

MR. FULLER: Objection, misstates evidence.

A. So I can only comment on the facts of which I know and what records exist. I don't make comments on hypothetical situations of whether it could have occurred and there was no documentation or it's lost

diligence, but that wasn't the program, and it was just one occurrence, then I don't think it's really faulty.

I think it requires that the company acted -- actually had to have some procedure in place to actually do due diligence investigations, not just one instance.

Q. But in your report you assume that there was no due diligence and that Dr. McCann then relied on that assumption, correct?

And so my question is very specific: If McKesson conducted sufficient due diligence on that first flagged order under its LDMP program, its CSMP program, its Section 55 program, you would agree sitting here today that the results that we see from Dr. McCann's analysis, they would be different?

MR. FULLER: Object to form, misstates the fact. The witness didn't make the assumption there was no due diligence. He's testified based on his opinion there's not

adequate due diligence.

A. That's hypothetical. I wouldn't say one -- one due diligence would reset it if the company's conduct continued along the same, the same level, so -- and my -- and my requirement to Dr. McCann was that during the entire time period, I did not see a sufficient due diligence to satisfy the regulatory requirements, so that's why it was ran during the whole time frame.

BY MR. EPPICH:

Q. How many due diligence investigations or analyses would be enough to be sufficient due diligence?

A. Every one of the suspicious orders.

Q. Did you review any of the flagged orders from Dr. McCann's analysis of McKesson?

A. No, sir.

Q. Do you intend to offer any opinions on whether the orders flagged by Dr. McCann are legitimate or suspicious?

A. If that requirement is required of me by the attorneys in the case, I would

complete that analysis. I don't have any independent intentions of doing that.

Q. Sitting here today, you have no opinions about the legitimacy of the flagged orders from Dr. McCann's analysis, correct?

MR. FULLER: That misstates his report.

A. It's -- Dr. McCann's report doesn't report orders, it just reports dosage units. It doesn't say how many orders. It doesn't say there was an analysis of each individual order.

It looked at them whether or not they violated the trigger that was provided for each one of them, and if it -- and then it moved forward without the -- because already knowing that there was insufficient due diligence.

BY MR. EPPICH:

Q. And you reviewed -- let me strike that.

Let's turn to page 74 of your report. On page 74, I'm looking at Section 6, the second paragraph in particular. The first sentence there says:

There is no more effective control to prevent diversion than blocking a suspicious order before it is shipped.

Did I read that correctly?

A. You did, sir.

Q. And that's because a blocked order of opioids remains safely in the vault of the distributor's warehouse, correct?

A. I guess you could make that assumption. It doesn't leave the control of the distributor and have the potential to be diverted, so I think that's probably the same statement, yes, sir.

Q. You'd agree that reporting the blocked order to DEA in a suspicious order report does not prevent the blocked order from being diverted, correct?

A. Well, that hypothetical wouldn't occur because if you block an order and report it, that doesn't -- unless you're saying that that causes a distribution, and if that causes the distribution without the effective due diligence, then no, that would not be true.

I would say that it would

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	MDL No. 2804
	)	Case No. 1:17-MD-2804
THIS DOCUMENT RELATES TO ALL CASES	)	Hon. Dan A. Polster

Tuesday, May 14, 2019

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

Videotaped Deposition of JAMES E. RAFALSKI, VOLUME 2, held at Weitz & Luxenburg PC, 3011 West Grand Avenue, Suite 2150, Detroit, Michigan, commencing at 8:25 a.m., on the above date, before Michael E. Miller, Fellow of the Academy of Professional Reporters, Registered Diplomate Reporter, Certified Realtime Reporter and Notary Public.

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deps@golkow.com

there were questions related to the summary data, I think I could answer any questions related to that data because it's obviously posted on the DEA website.

Q. All right. I'd like you to turn to page 37 of your report, which I believe you have in front of you.

A. It is.

Q. And I understand it's Exhibit 16.

A. It is.

Q. Pages 37 through 40 of your report are within a section that starts on page 36.

Do you see that?

A. Yes, ma'am, titled Maintenance of Effective Controls Against Diversion of Controlled Substances.

Q. Yeah. And at the top of page 37, just before the bullet list starts, you wrote: Included below are some key components that one would expect to see an operational system designed to maintain effective controls against diversion.

Did I read that correctly?

A. You did, ma'am.

Q. Okay. Then following that statement at the top of page 37 of your report, you've included a list, a bullet-pointed list, several levels of bullet points, that carries all the way over to page 40.

Would you agree with that?

A. Yes, ma'am.

Q. Is that list of bullet points on pages 37 to 40, is it your opinion that those are requirements to be included in a distributor's suspicious order monitoring system?

A. No, I wouldn't say they're requirements. As the initial statement said, they would -- I would expect to see those as components of an operational system, but it's not a -- not dictating or saying that they're a requirement by the government.

Q. You're not saying that any of those bullet points on pages 37 through 40 are requirements, not a single one of them?

A. Oh, to meet the maintenance of effective controls, I think they're all

requirements, but I understood your question to say is this something that would be a regulatory requirement, that something would be in a regulation, these specific things.

Q. Let me --

A. Based on my experience, these are all the things that I believe should be present in a functioning operational suspicious order system.

Q. Let me see if I understand your testimony.

You're saying that the list of components on pages 37 to 40 are not requirements under the DEA's suspicious order monitoring regulation; is that correct? That's part one.

A. Well, the word "requirement" is kind of the word that I'm thinking about. So if you're trying to say that it's a mandate, I would say in order for me to say that it's an operational system, then these things would need to be present. If they weren't present, it wouldn't be an operational system.

So if you were to say that you

could take this and say the DEA said you must have these things in your system, there's a possibility that maybe one of them wouldn't be there and it still could function.

So I wouldn't say -- I don't want to say that this is dictating exactly what has to be in a system, but in my experience in reviewing a lot of systems, these would be the key components I would expect to see.

Q. All right. Now I'm more confused than I was before.

A. Okay.

Q. If I understand what you're saying, it seems like you're saying the bullet list at pages 37 to 40 are not required by the DEA's suspicious order monitoring regulation, but they are required by the maintenance of effective controls against diversion?

A. Let me start over. So --

Q. Just -- can you just say yes or no? I really want to just know if I'm following you.

MR. FULLER: No, he can explain

clarify.

MS. SWIFT: All right. Let me see if I can clean this up.

MR. FULLER: Sure.

BY MS. SWIFT:

Q. There was a pronoun in the question that I thought Mike was correcting.

When you say -- let's see. The maintenance of effective controls is in the large regulation which is above, or the hierarchy, did you mean 1301.74(a)?

A. Well, that is the regulation. I'm also aware that the laws in 823, USC 823.

Q. As your counsel just reminded you?

A. Well, I've always known that whether counsel reminded me or not.

Q. Understood. Understood.

A. So that's the regulation, it's both the law regulation and the law. Only -- 1301.74(b) is only a regulation, which is part of the security program, which is part of maintenance of effective controls.

So it's kind of bulleted so that the top regulation is maintenance of

effective controls. Falling under that is suspicious order system.

Q. So the list on 37 to 40, these are not requirements under 1301.74(b), the suspicious order monitoring regulation, correct?

A. So I'd like to answer that by saying I believe these are all components, which would be necessary to have an effective suspicious monitoring -- a suspicious order monitoring system.

Q. And with respect, sir, that's not what I asked you.

Are the bullet list components on pages 37 to 40 of your report required under 1301.74(b), the suspicious order monitoring --

A. Yes, they are.

Q. Okay. All of them?

A. Yes.

Q. Okay. Great. Thanks.

Is it possible to have a compliant suspicious order monitoring system without all of these components?

A. Yes, I think it would be

possible.

Q. But they are all requirements?

A. Based on -- depending on the scope of the business that's the customer and based on the scope of activity of the distributor, I would say that some of these -- there could be some of these that would not be necessary. But I'd also say that there may be some that aren't identified on this list. And also, based on the fact that the distribution activity is not static and it changes.

Q. So if I'm following you, all of the bullet-listed components on pages 37 to 40 are, in fact, required under 1301.74(b), but you could have a compliant suspicious order monitoring system without all of these compliant -- components, and, in fact, there may be other components that are required under 1301.74(b) that are not included in this list.

Do I have all that, correct, sir?

A. I believe that's correct, yes.

Q. Okay.

A. I'm not saying this is an exclusive list and there might not be other things that I have not considered or might come up based on the type of business activities that are involved.

Q. On page 39, if you would take a look, please. You say, the top bullet, that: A robust and well-documented due diligence program is key.

And then it goes on from there and provides components that you say you would like to see in a due diligence compliance program for suspicious orders, correct, sir?

A. Yes, ma'am.

Q. Is it your opinion that a distributor has to do all of the diligence steps listed here in order to comply with the law?

A. Yes, ma'am.

Q. All right. I want you to hold on to these pages of your report for a minute, please. And I'm going to hand you a document. This will be Exhibit 19.

(Whereupon, Deposition Exhibit

Rafalski-19, 5/17/06 Corso Letter, WAGMDL00753477 - WAGMDL00753479, was marked for identification.)

MR. FULLER: Are they all the same?

MS. SWIFT: They're all the same.

MR. FULLER: Okay.

BY MS. SWIFT:

Q. Okay. Exhibit 19 is a May 17th, 2006 letter from the DEA to Todd Polarolo at Walgreens in Perrysburg, Ohio, correct, sir?

A. Yes.

Q. Do you recognize this as a letter the DEA sent to Walgreens after an audit of Walgreens' Perrysburg, Ohio distribution center in 2006?

A. I recognize it only based on my review of documents for preparation of this is the first time I've seen this, from my report.

Q. You're mentioned in the first paragraph of the May 17th, 2006 letter, correct, sir?

A. I was there, yes, ma'am.

Q. When you were at the Detroit field office, you were involved in this audit of Walgreens' Perrysburg, Ohio distribution center, correct, sir?

A. Yes, ma'am.

Q. This was a routine audit before Walgreens' Perrysburg distribution center started distributing Schedule II controlled substances in early 2007, correct, sir?

A. No, that's not correct.

Q. What is the basis of your statement that that's not correct?

A. It's a regulatory audit, but it was just scheduled as part of the work plan program. It wasn't in response to the second part of your question, Schedule II controlled substance authorization.

Q. Are you offering that testimony based on your personal involvement with an investigation of Walgreens while you were at the DEA?

MR. FULLER: Again, I remind you, Mr. Rafalski, that your authorization does not and

specifically addresses the fact that Walgreens was an investigation that you conducted that you're not authorized to talk about it based on your personal knowledge. Just from what information you gained in this litigation.

BY MS. SWIFT:

Q. Do you want to retract the testimony that you gave a moment ago?

A. Yes, thank you.

Q. This 2006 letter that I marked as Exhibit 19 that the DEA sent to Walgreens does not include the three pages of guidance on what Walgreens' suspicious order monitoring system should look like that you included in your report at pages 37 to 40, does it, sir?

A. It does not.

Q. This 2006 letter the DEA sent Walgreens, it says what DEA thought Walgreens was doing wrong. It doesn't provide an explanation of what we should do to do it right, correct, sir?

A. That's an accurate description

of what the letter says, yes, ma'am.

Q. You did not provide to Walgreens the three pages of requirements that are included in your report. You didn't give those to Walgreens in 2006, correct, sir?

MR. FULLER: Object to form. Don't answer that, that would be based on your own investigation, not knowledge of this case.

BY MS. SWIFT:

Q. You're not going to come to trial and say you provided these three pages of guidance to Walgreens in 2006, correct, sir?

A. If the Touhy is still in place, I would say that I would not be able to testify to that.

Q. You worked with the folks at Walgreens' Ohio distribution center for several years, correct, sir?

A. I'll respond to that question by saying as part of my assignments as a diversion investigator, I went on-site to that facility several times. I'm not sure I

would agree that I worked with them, but I was present at the registered location.

Q. You worked with Steve Kneller a fair amount? He works at the Perrysburg distribution center.

A. I know the name Mr. Kneller. I think it's K-N-E-L-L-E-R?

Q. Correct.

A. I recognize that he was the person that if I was on-site, that he would be the person that I would have contact with, yes, ma'am.

Q. Did you know Justin Joseph as well?

A. There was another -- there was one other person with him, and I don't know that that was Mr. Joseph. I do remember who Mr. Polarolo was, but I'm not sure.

Q. You never told Steve or Justin or Todd Polarolo or anybody else at the Perrysburg distribution center, here's a list of things your suspicious order monitoring system is supposed to have, did you, sir?

MR. FULLER: Object to form.

I'd remind you of your Touhy

authorization.

THE WITNESS: Based on the Touhy, I'm not going to answer.

BY MS. SWIFT:

Q. You don't say anything like that -- strike that.

The DEA doesn't say anything like that in this 2006 letter, correct, sir?

A. None of the things that are in the pages we've discussed is present in this letter.

Q. You also don't say in your report that you told Walgreens at any point in time, here's what your suspicious order monitoring system is supposed to look like?

A. My report does not indicate that I told them that, that's a correct statement.

Q. Did anything prevent you from providing these pages of guidance on suspicious order monitoring to Walgreens in 2006 or at any other point in time?

MR. FULLER: Object to form.

If it would deal with internal DEA policies and what agents were and were

not allowed to do, you're not authorized to answer that.

THE WITNESS: I think based on the Touhy, I'm not going to answer that question.

BY MS. SWIFT:

Q. Your position today, 13 years after this 2006 letter from the DEA to Walgreens, your position today after you've been hired by the plaintiffs' lawyers and paid to offer opinions in this case is that these pages of your report, these three pages listing these requirements, are all obligated by law; is that right, sir?

A. I think I've always believed they were obligated by the law. I would probably say in 2006, the environment in regards to the opioid crisis and diversion, probably the environments changed.

So I'm not sure that all of these would have been something that I would have used or been aware of at that time.

I think this is fluid and it's changed over a period of years, but generally, the answer to your question...

Q. My question is simply: Do you agree with me that the formula in Appendix E(3) that Walgreens used to report suspicious orders from 2007 to 2012 is not the same as the customer grouping formula Walgreens was using in 2006?

A. Well, this statement just goes to say that they used the same multiplier, so the three multiplier is the same as the E(3) as it is in the area referenced in the prior time period.

Q. The two formulas are not the same, correct, sir?

A. The formulas are not, but the multiplier is.

Q. Okay. That's all I'm trying to get an understanding from you is whether the customer grouping formula that Walgreens was using when it received the 2006 letter from the DEA is the same or different from the formula it changed to use afterwards?

A. There's no customer grouping in the subsequent years --

Q. Thank you.

A. -- starting in 2007.

Q. You didn't do -- well, strike that.

You don't say in your report that you or anyone else at the DEA ever told Walgreens not to use the formula found in Appendix E(3) of the Chemical Handler's Manual, correct, sir?

A. Appendix E(3) was never discussed in my presence with Walgreens.

Q. The DEA's 2006 letter to Walgreens doesn't say not to use the E(3) formula, correct?

A. I still stand by my previous statement. The E(3) appendix was never discussed by me or anyone in my presence the whole time I was at Walgreens.

Q. And it's not mentioned in this letter either?

A. It is not mentioned in that letter.

Q. All right. I'd like you to turn to page 40 of your report, please. Is that 40?

A. I'm sorry.

Q. I believe you testified

yesterday that you did not review any of the flagged orders from Dr. McCann's analysis; is that correct?

A. I think my testimony in that area was any specific orders. That would be correct of what my testimony was, yes.

Q. You did not do any analysis to see whether any specific suspicious order caused the diversion of any specific pills for nonmedical use, correct?

A. In regards to Dr. McCann's --

Q. Correct.

A. That would be a correct statement. I didn't do a specific order of a specific drug, if I understand your question properly.

Q. Well, you asked for a clarification of whether I was speaking about Dr. McCann's analysis.

You didn't do any analysis to see whether any specific suspicious order caused the diversion of any specific pills, correct?

MR. FULLER: Object to form.

A. I think that's an accurate

statement.

BY MS. SWIFT:

Q. You testified yesterday that you endorsed Flagging Method A, which you can see at the top of page 41 of your report. Because it -- is that correct?

A. I think that's an accurate statement. It was -- I endorsed it because it was utilized by the Masters Pharmaceutical.

Q. Is that the only reason you endorsed Flagging Method A?

A. No, that wouldn't be the only reason, no, ma'am.

Q. Did any of the plaintiffs' lawyers instruct or suggest to you that you use Flagging Method A?

A. No.

Q. What other reasons did you endorse Flagging Method A?

A. One, it was part of one of the investigations I conducted, so I was familiar with it. I believe it was discussed at an administrative hearing with the DEA, subsequently reviewed by the D.C. Court, and

there was a ruling on it from the D.C. Court and also the one ruling that it was part of this litigation, I think...

Q. Discovery Ruling 12?

A. Yes, Discovery Ruling 12. So I think it's had some scrutiny. I think it would be the proper one. And that's...

Q. What analysis, if any, did you undertake to test each of the five flagging methodologies and their ability to identify suspicious orders?

A. Could you say that one more time, please?

Q. Sure.

What analysis, if any, did you do to test the five flagging methodologies in your report and their ability to identify suspicious orders?

A. I didn't personally do any tests. I'm aware that they could have been done by Dr. McCann, but I didn't personally do them.

Q. Do you know whether Dr. McCann conducted any analysis at all to test the five flagging methodologies and their ability

to identify suspicious orders?

MR. FULLER: Object to form.

A. He had an extensive report. I'm not sure on that. I believe he did, but I'm not sure.

BY MS. SWIFT:

Q. Why do you believe Dr. McCann did any analysis at all to test the five flagging methodologies and their ability to identify suspicious orders?

MR. FULLER: Object to form.

A. Well, I think that's what this does.

BY MS. SWIFT:

Q. You think that's what what does?

A. I think the methodology of A identifies suspicious orders based on that methodology, and then it provides them in dosage units. So I think ultimately, for these dosage units to appear on this page, there had to be flagged suspicious orders.

Q. You're pointing to a page of your report, not Dr. McCann's report, correct, sir?

A. Right. But -- yes. But for me to see this --

MR. FULLER: Form.

A. -- I would have to know that this methodology had flagged suspicious orders because that's the only way the dosage units could appear on this chart.

BY MS. SWIFT:

Q. Did you read Dr. McCann's report?

A. I did.

Q. When did you read Dr. McCann's report?

A. Sometime after he had submitted it and reviewed his charts resulting from his analysis.

Q. Did you read Dr. McCann's report before you put together this section of your report that appears at page 41?

A. No.

Q. Flagging Methodology A -- I'm still at page 41 of your report. I'm going to focus on the rows of these tables that we've got here that relate to my client, which is Walgreens, okay?

A. Sure. Yes, ma'am.

Q. Flagging Methodology A flagged 95% of all Walgreens orders by dosage unit of oxycodone and hydrocodone, correct, sir?

A. Yes, ma'am.

Q. Is it your professional opinion to a reasonable degree of certainty that 95% of Walgreens orders should not have been shipped?

A. Based on the conduct of Walgreens and the failure to do due diligence on suspicious orders, yes, ma'am.

Q. Is it your opinion to a reasonable degree of certainty that only 5% of orders from Walgreens stores should have been shipped and available to fill prescriptions for Walgreens patients?

A. Well, that would be the converse of this statement, but based on their conduct -- I'll go back again, based on their conduct and their failure to do diligence after identification of suspicious orders, the only conclusion I can draw is that subsequent to that act, all of the controlled substances were diverted.

Q. So that's a yes, your opinion is that only 5% of orders from Walgreens stores should have been shipped and available to fill prescriptions for Walgreens patients?

MR. FULLER: Object to form.

A. I really don't know because Walgreens didn't conduct the proper due diligence. But based on the methodology and how I applied it, that's the results of the methodology.

BY MS. SWIFT:

Q. You don't know whether it's true that only 5% of orders from Walgreens stores should have been shipped and available for prescriptions to be filled for Walgreens patients?

A. I guess you would draw that conclusion based on 95.3% based on the conduct of Walgreens, yes, ma'am.

Q. You would draw the conclusion --

A. I would draw the conclusion based on --

Q. Let me ask the question so the record is clear.

You would draw the conclusion that only 5% of Walgreens orders should have been shipped so that prescriptions could be filled for Walgreens patients?

MR. FULLER: Object to form, asked and answered. You've asked it twice now or three times, probably.

A. Same as my previous statement. Based on Walgreens' conduct in regards to applying this methodology, that would be a correct statement, yes, ma'am.

BY MS. SWIFT:

Q. You didn't do any analysis of how many people would not have gotten their medication if 95% of Walgreens orders had not shipped, correct, sir?

A. I did not.

Q. You didn't do any analysis of how many legitimate prescriptions would have gone unfilled if 95% of Walgreens orders had not been shipped, correct, sir?

A. I did not do that analysis, no, ma'am.

Q. In your report, you don't offer an opinion on the legitimacy of any of the

other flagging methods you talk about, correct?

A. That's correct.

Q. You didn't offer any criticisms of any of the five flagging methods in your report, correct, sir?

A. Oh, I think I did.

Q. Where did you offer criticisms of any of the five flagging methods in your report?

A. You're saying the methodology --

Q. Correct.

A. -- for example, the three times?

Q. There are five methodologies --

MR. FULLER: Go ahead and finish your answer, Raf.

MS. SWIFT: Yes, I was answering his question. There was no pending question.

A. Yes. Throughout my report, I think there's reviews of these methodologies, and I think I'm critical of each of the methodologies, with the exception of

data that it would have to indicate specific orders which would identify those pharmacies.

Now, whether he looked at them specifically to that pharmacy, but based on your question, just the analysis of the ARCOS data, that -- that actually would occur because each order would be specific to a pharmacy.

He didn't -- if I understand your question, he didn't look at them in terms of each specific pharmacy, but the nature of the analysis, it is by the pharmacy by the orders.

Q. You did not perform an analysis to see whether Walgreens performed diligence on any of the actual orders that flagged on any of your five methodologies in Mr. McCann's analysis, correct?

A. Well, my investigation and opinion of Walgreens does state that in regards to the due diligence topic.

Q. Listen to my question. That's not what I'm asking about.

A. Okay.

Q. We'll get to the stuff you say

in your report about the due diligence that Walgreens did.

You didn't perform an analysis to see whether Walgreens performed diligence on any of the specific orders that flagged on any of these five methodologies, correct, sir?

A. I'm not aware of any due diligence for those orders, that's correct.

Q. That's not what I asked.

A. I didn't -- I didn't specifically go to McCann's report and look at each order of Dr. McCann's and try to find due diligence. I just looked at the scope of the due diligence by Walgreens.

Q. You didn't go to Dr. McCann's report and look at any order of -- that flagged on any of the analyses.

A. That's a correct statement.

Q. For any of the five flagging methods that you talk about, did you consider the impact of stocking a new store's shelves?

A. I did not take that specific incident into consideration, but in my review of due diligence records, I didn't find

anything that would indicate that that had occurred.

Q. Did you consider whether any of the five flagging methods that you talk about could flag an order for a store before the store even opened for business, just based on the stocking of the store's shelves? Do you know whether that happened?

A. I'm not aware that that had happened.

Q. Did you read Dr. McCann's testimony from this past Friday that using at least some of these five flagging methods, an order to stock a new store's shelves could be flagged?

A. I don't recall reading that in his testimony, no, ma'am.

Q. Did you read his testimony yet? I know it was just the other day.

A. I've read so many. I don't believe so.

Q. I will represent to you, and you can check the transcript, that Dr. McCann testified that for low-volume stores, the store might never have another order as big

an economist or I've never talked to anyone with the purpose of giving these things to an economist. So I don't want to imply my testimony is I've never talked to an economist. I'm not aware of it, but I'm just kind of protecting the fact that if I did, I wasn't even aware of it.

Q. You never explained the data in your report to anyone for the purpose of them taking that data and using it to calculate damages in this litigation?

A. I have never done that.

Q. You testified yesterday that you provided the five flagging methods discussed in your report -- you provided those to plaintiffs' counsel by phone I believe, you said to -- provided them to Mr. Farrell.

Do you remember that testimony?

A. I think that question was the first time that I talked to somebody about it. So --

Q. I'm trying to get at how the --

MR. FULLER: Object to the form of the last question. I'm sorry.

BY MS. SWIFT:

Q. I'm trying to get at how the five flagging methods made their way from you to Dr. McCann.

Do you have any idea how that happened?

A. There was a couple of different discussions with the plaintiff attorneys. I'm not sure who relayed it to Dr. McCann. I discussed it with Paul Farrell, Mr. Farrell a couple of times; also with Mr. Fuller. I'm not sure who relayed it to him, but I discussed the methodologies and how I wanted them applied.

Q. All of those conversations were verbal, is that correct, not in writing?

A. There was nothing in writing, and they were verbal, either in person or on a telephone.

Q. I'm going to hand you what I'll mark as Exhibit 20.

MS. SWIFT: And, Counsel, I apologize, I only have one extra copy. Blame the hotel. I'm not even going to have a copy for myself.

(Whereupon, Deposition Exhibit Rafalski-20, Plaintiffs' Responses to the Amended and Clarified Discovery Ruling 12 Supplemental Interrogatory Issued to Plaintiffs, was marked for identification.)

BY MS. SWIFT:

Q. Do you have that in front of you, sir?

A. I do.

THE WITNESS: Trade you.

Sorry.

BY MS. SWIFT:

Q. Well, first of all, have you ever seen the document that I've marked as Exhibit 20?

A. I have, yes, ma'am.

Q. The document I marked as Exhibit 20 is a set of interrogatory responses served by the plaintiffs on January 25th, 2019, and if you go to -- I believe it's the sixth page -- there's a list of flagging methodologies prepared at the very end of the written interrogatory response. Keep going.

MR. FULLER: It's not page numbered.

MS. SWIFT: I noticed that, Mike.

MR. FULLER: We'll blame Mr. Moody or Mr. Farrell.

BY MS. SWIFT:

Q. Do you have a list in front of you, Mr. Rafalski, that lists five flagging methodologies in the plaintiffs' interrogatory response from January 25th?

A. I do.

Q. Are these your five flagging methodologies?

A. Yes, ma'am.

Q. Which one is based on the Masters case?

A. 4.

Q. Am I correct based on your testimony today and yesterday that you're not planning to come to trial and offer testimony about any of the flagging methods except the Masters method?

A. No, I don't think that's my testimony.

Q. Okay. All right. Turning back to your report -- you can set that aside, we're done with it -- page 42, I'd like to take a look at, please.

MR. FULLER: I'm sorry, Counsel, what page?

MS. SWIFT: 42.

BY MS. SWIFT:

Q. If you had picked Flagging Method B that's identified at the top of page 42, instead of Method A, the Masters method, what data would you have presented for Walgreens?

MR. FULLER: Object to form.

A. I don't understand that question.

BY MS. SWIFT:

Q. Fair enough.

A. I think I did pick Methodology B, but so I don't understand.

Q. Well, you said you endorsed Method A and that's the only method you endorsed, correct, because of the Masters case and some other reasons?

A. Well, I think I make that

Q. You didn't --
A. -- trigger.
Q. You can't vouch for the accuracy of any of the numbers that appear in these tables at pages 41 to 45 of your report, correct, sir?
A. Mr. McCann would have to testify to the accuracy. He did the analysis.
Q. You just relied on what Mr. McCann provided, correct, sir?
A. Yes, I did.
Q. You were -- strike that.
You don't have an opinion about whether any particular order that you identified or that Dr. McCann identified as suspicious was diverted to an illicit channel, correct, sir?
A. Well, I think based on the methodologies and the lack of due diligence, I think my -- these say that those were diverted.
Q. My question was a little bit different.
A. Okay.

Q. You don't have an opinion about whether any particular order -- you didn't look at any particular order to see whether it was diverted to an illicit channel?

A. I did not --

Q. Okay.

A. -- analyze all the orders and try to find one or locate one that was diverted.

Q. You didn't analyze any of the orders, correct, sir?

A. That's correct.

Q. You have no opinion about whether any particular order that was flagged as suspicious led to someone's addiction, overdose or death, correct, sir?

A. As of today, I have no opinion on that matter.

Q. Do you plan on coming up with that opinion at some point after today?

A. I can't rule that out if I'm asked to look at that or I'm provided some information I could review that would -- that would indicate that. So I can't rule out that that would occur.

Q. If a prescription was legitimate, the pharmacist was obligated to fill it, correct, sir?

MR. FULLER: Form.

A. I don't think the DEA speaks to that, whether they're obligated to fill a prescription.

BY MS. SWIFT:

Q. Do you know one way or the other whether --

A. If the DEA speaks to that topic?

Q. No, sorry.

Do you know whether pharmacists are obligated by their professional responsibilities to fill prescriptions that they have determined are legitimate? Maybe you don't know one way or the other.

A. Let me think. I don't know that, the answer to that question.

Q. All right. Turn, if you would, please, to page 114 of your report.

A. Can I qualify my last answer, quickly?

Q. Sure.

Q. Is that the page 856 that you cite in your report at page 114?

A. Yes, ma'am.

Q. Okay. This Appendix 10 from McCann's report is what you relied on to determine total volume of oxycodone and hydrocodone that Walgreens shipped into Cuyahoga and Summit Counties; is that right?

A. Yes, ma'am.

Q. You only talk about oxycodone and hydrocodone in your report, correct?

A. Yes, ma'am.

Q. Am I right that you don't have any opinions about any other opioid pain medications besides oxy and hydro?

A. As of today I do not because I was not requested to do any analysis on those other drugs.

Q. After -- turn back to page 1 of Exhibit 21. The page 1 of Exhibit 21 is a table that shows overall numbers, Total Shipments to Cuyahoga identified by Methodology, Common Sense Method, Maximum Monthly Trailing Six-Month Pharmacy Specific Threshold, Walgreens to All Buyers, 1996 to

2018, correct?

A. Yes.

Q. And it's a table that shows numbers broken out by drug and by transaction, dosage units, MME, and base weight, correct?

A. Yes.

Q. After the table on page 1 of Appendix 10, there's a series of bar graphs showing, in the aggregate, Walgreens shipments of oxy and hydro to its pharmacies in the aggregate, correct?

A. Yes, ma'am.

Q. None of these charts shows any data for any individual Walgreens pharmacy, correct?

MR. FULLER: Object to form.

A. That's an accurate statement, but they're all built upon individual orders.

BY MS. SWIFT:

Q. I understand.

A. Okay.

Q. I'm just saying, when you're flipping through Dr. McCann's charts that display the results of his flagging

methodologies, you can't tell anything about any individual pharmacy, correct?

A. I cannot by looking at these charts.

Q. Do you know how many Walgreens stores there are in Cuyahoga County?

A. I do not.

Q. How about Summit County?

A. I do not.

Q. Do you know anything about the geographic locations of any of Walgreens' pharmacies in Summit or Cuyahoga County, other than the fact that they're in those counties?

A. It doesn't appear in my opinion, but during my review of data, I did at one point take a look by just using the Internet, Googling and looking at some of the locations, but I didn't formulate a report on that.

So I won't say that I never did that, but I don't have any records or documents that would record exactly the distances and the locations.

Q. You also didn't include in your

report anything about the specific customer base for any individual Walgreens pharmacy, correct, sir?

A. I did not.

Q. Do you know how many of the Walgreens pharmacies in Cuyahoga and Summit County are on corner lots?

A. I do not.

Q. Do you know how many of the Walgreens pharmacy in Summit and Cuyahoga Counties are freestanding locations with their own dedicated parking and a drive-through window?

A. I do not.

Q. Do you know how much oxycodone or hydrocodone Walgreens distribution centers shipped to any one of those Walgreens pharmacies?

A. I do not. I had not done that analysis up to today.

Q. You can't tell any of that from the charts that are in Appendix 10, correct, sir?

A. That's correct.

Q. All right. You can set that

one aside.

Turn, if you would, please, sir, to page 117 of your report. This is a section within the Walgreens section about the due diligence that you believe Walgreens conducted, correct?

A. Yes, ma'am.

Q. Now, as I understand it, it's your opinion that because you only saw a limited number of e-mails about due diligence that Walgreens performed 10, 12, 13 years ago, that that means Walgreens performed no other due diligence; is that correct?

A. Not that was brought to my attention in trying to formulate my opinion.

Q. And in formulating your opinion, you determined that Walgreens had only conducted limited due diligence because you only saw documentation of limited due diligence, correct?

A. That's the only basis I could use to form my opinion.

Q. You based your -- well, let me ask you this.

Did you read any of the

this one?

MS. SWIFT: Yep.

(Comments off the stenographic record.)

BY MS. SWIFT:

Q. I'm marking as Exhibit 25 an excerpt of McCann's Appendix 11, and like with the others today, what we've done is pulled out the pages that relate to Walgreens, okay?

A. Okay.

Q. Have you ever seen the charts that appear in Exhibit 25?

A. I believe I looked at these because they were part of the methodology analysis.

Q. Who shared them with you?

A. I believe Mr. Elkins would have provided them to me.

Q. The plaintiffs' lawyer, Mr. Elkins?

A. Yes.

Q. When did Mr. Elkins share the charts in Exhibit 25 with you?

A. I don't recall.

Q. You didn't cite or attach any of these charts to your report, correct, sir?
A. No, I don't believe I did.
Q. You've never talked to Dr. McCann about any of the charts in his report; am I right about that?
A. That's correct.
Q. Okay. All right. You can set those aside. That's all I was going to do with that one.
Turn, if you would, please, to page 115 of your report. Page 115 is within the Walgreens section and talks about an investigation of the Jupiter distribution center in Florida, correct, sir?
A. It does at the bottom of the page.
Q. You didn't have any personal involvement in the Jupiter, Florida investigation of Walgreens, correct?
A. No, ma'am, I don't believe so.
Q. To the extent that you have opinions about the Jupiter, Florida investigation, you're relying entirely on the Order to Show Cause and related documents

attached to Walgreens' 2013 settlement agreement with the DEA -- is that right -- cited in note 493?

A. Yes, ma'am.

Q. Okay. Did you -- in preparing for your -- to write your report, did you review any of the documents showing Walgreens' efforts to cooperate with Florida DEA and local law enforcement in 2010 and 2011?

Do you remember anything like that?

A. I don't remember reviewing any records or communications in regards to that, no, ma'am.

Q. In preparing your report, did you review any of the documents produced by the plaintiffs, Cuyahoga and Summit County, showing Walgreens' pharmacists notifying local law enforcement when they suspected diversion?

A. No, ma'am.

Q. Turn, if you would, please, to page 118. I'll direct your attention to the last paragraph on the page that starts

A. Yes.

Q. But if you look at the CVS line for Cuyahoga County on page 41, you've got 95.7% of the total dosage units are flagged using the trailing six-month threshold?

A. I do.

Q. And you have 94% of the total dosage units in Summit County that are flagging, right?

A. I do.

Q. And if you remove the assumption that everything after one failed due diligence effort flags, do you know what those numbers go down to?

A. I do not.

Q. You have no clue?

A. I have no clue.

Q. If I told you that in Summit County they go down to 4.3% rather than 94%, and they go down to 4.6% rather than 95% in Cuyahoga, would that surprise you?

A. I wouldn't have a comment on those figures.

Q. Now, you also have testified already a little bit about whether or not you

reviewed any particular orders, and I think your answer in substance is no, you didn't review any particular orders that might or might not have been suspicious.

Is that generally true?

A. That's generally true, that's my recollection is I answered that way previously, too, yes, sir.

Q. And with respect to any of the orders that are flagged by these methodologies under your and Mr. McCann's analysis, you don't know what happened to any of the drugs that were actually shipped and delivered to CVS Pharmacies?

A. I don't have any direct knowledge of what happened to any of the drugs that were distributed to each of the pharmacies. I didn't conduct any analysis as of today that would give me that knowledge.

Q. And you don't know whether -- I understand that your opinion is that the due diligence was insufficient by CVS, and we'll get to that in a minute.

But you don't know whether any of these orders would have cleared a due

diligence investigation that does meet your exacting standards, do you?

A. Could you say that one more time, I'm sorry?

Q. I'm just saying you don't know whether any of the orders that are flagged using your and Mr. McCann's methodologies for CVS would have been cleared using what you would say is an adequate due diligence process. You haven't done that analysis.

A. So I think what you're asking, is it a hypothetical question?

Q. Yes.

A. Okay.

Q. Well, no, actually it's not. You don't know. I'm asking you. You don't know?

A. Well, I guess you're asking me to assume that if CVS had an adequate due diligence system in place and they conducted it? Is that the question? Maybe I don't understand the question.

Q. Let's -- if you took your standards for a due diligence system --

A. Okay.

that. It's just that I wasn't tasked to provide that methodology in regards to manufacturers at this time.

Q. I understand. But your report doesn't identify any suspicious orders that were submitted by distributors to manufacturers.

A. My report would only identify those orders that the manufacturers have identified. I don't make any independent calculations or apply any algorithms to identify it outside of what's in my report stated as I've discovered as part of this discovery.

Q. Okay. So other than the reports that the manufacturers themselves reported to DEA, you have not identified any suspicious orders submitted by distributors to manufacturers, correct?

A. Can I ask a clarification? Are you talking about an individual order or are you talking about conduct?

Q. I'm talking about individual orders.

A. I have not done that as we sit

here today, no, sir.

Q. Okay. So your report does not identify any shipments by manufacturers to distributors that you claim should have been reported as suspicious?

A. My opinion goes to whether or not there were effective -- or suspicious orders, effective suspicious order systems in place and/or the maintenance of effective controls, the due diligence. I do not do any calculations that would identify any specific orders.

Q. Okay. So just to be clear, in response to my question, your report does not identify any shipments by manufacturers to distributors that you claim should have been reported as suspicious, correct?

A. I think there's some instances in my report, there was -- there may be a description of a relationship or some transactions between a -- let me think a second.

Q. Uh-huh.

A. Because I have all of the different companies.

(Document review.)

A. I don't believe so, no, sir.

BY MR. O'CONNOR:

Q. Okay. And at trial, do you intend to offer any opinion regarding whether any particular order submitted to a manufacturer was suspicious?

A. If I'm requested to do that analysis by counsel, I guess that would be a possibility. I haven't done the analysis as today, so I couldn't offer that opinion.

Q. So as you sit here today, you do not have an opinion on whether any particular order that was shipped by a manufacturer was suspicious?

A. I think I have an opinion.

Q. But you haven't identified any order, correct?

A. I have not identified a specific order, but I have an opinion on the conduct.

Q. And are you offering any opinion in this litigation that any particular order that was shipped into Summit or Cuyahoga Counties was suspicious?

A. Yes.

Q. Okay. And are you offering any opinion in this litigation that any particular order shipped by a manufacturer into Summit or Cuyahoga County was suspicious?

A. I'm sorry, shipped by a manufacturer --

Q. Correct.

A. -- to a distributor?

Q. That's right. To -- to someone in Cuyahoga or Summit County.

A. No, sir.

Q. Okay. With respect to a manufacturer, what is a suspicious order?

A. Well, if a manufacturer has conducted a sufficient due diligence or onboarding process and they've evaluated the scope of their customers' business and the needs, they would establish a pattern, and that pattern would give them an idea of initially the volume of drugs they need to purchase.

Now, if it's brand-new customer -- yours is kind of a hypothetical.

If it's a brand-new customer, there's not a pattern or a frequency, but they would start out with what they assess as a legitimate volume, and they would monitor that volume, and if a customer exceeded that, that should trigger as an unusual size.

But to give you just a general definition, it's kind of a broad topic because it depends on the scope of business of the manufacturer, of the customer, the type of products, the needs, so the -- prior to ever shipping an order, the importance is to understand what the legitimate needs is of a customer.

Q. Yesterday you testified that it was important to understand what a usual order was so that you could determine what a suspicious order was.

Do you generally recall that testimony?

A. I think that's a general description. I think we were discussing the size, so I think before you would know an unusual size, you would need to know the usual size.

Q. What does that term mean?

MR. FULLER: Form.

A. Well, manufacturers are in a unique position at the top of the distribution chain, that their products pass through distributors down to pharmacies.

So there's a couple concepts within that know your customer's customer. There's, of course, if you have the information that you already have the ability to know, things like chargebacks and IQVIA, that's an example of information, know your -- you know, you know your customer's customer.

Secondly, a manufacturer would have the responsibility under the maintenance of effective controls to do an analysis of who their customers are, which would be the distributors.

So it would be incomplete to go do an analysis on them when they don't have an understanding of where their products would ultimately go.

BY MR. O'CONNOR:

Q. If a manufacturer wanted to

understand what this idea of know your customer's customer meant, it couldn't look in the regulations, could it, because it's not there?

MR. FULLER: Form.

A. I think it's encompassed in the maintenance of effective controls.

BY MR. O'CONNOR:

Q. But to be clear, the maintenance of effective controls regulation does not mention anything about knowing your customer's customer, does it?

A. It doesn't give any specific guidance, but I think what it does is it puts a manufacturer or any registrant on notice that their continued use of a DEA registration requires them to take steps to prevent diversion, and I believe that getting that information is one of those steps.

But so just -- just so it -- but I guess if your question is does it specifically say that term? It does not.

Q. And DEA never issued any guidance to manufacturers informing them of their supposed obligation to monitor -- or to

know their customer's customers, correct?

MR. FULLER: Form.

A. I know I've reviewed where it was presented at some training, but I'm not sure if that was by an industry or a consultant.

BY MR. O'CONNOR:

Q. DEA --

A. So I'll say no.

Q. DEA --

A. I'm not aware of it. At least I'm not aware they've done it. I'm not saying they have not done it.

Q. DEA never published guidance in the Federal Register saying anything about knowing your customer's customer, did it?

A. They have not done that.

Q. Okay. And they never sent a letter to all manufacturers, for example, saying they were to know their customer's customer, did they?

A. I'd like to look at the 2007 letter. I think it may say all relevant transaction information, and I would consider that relevant transaction information.

prescribed in the MOA can be greater than the duties imposed by statute, fair?

A. No, I don't agree with that. I think under maintenance of effective controls, that's a broad regulation, and I think all of these things fit under there.

I think I could -- I could hold another manufacturer, if I was still a DEA diversion investigator. I think the statements entered because it kind of affirms that that is a -- to me, that they acknowledge that that is their responsibility, because I wouldn't expect them to do it if they didn't think it was.

Q. Just to be clear, are you saying that every duty that's imposed on any registrant through a memorandum of agreement is by definition also required by the law?

MR. FULLER: Form.

A. Yes.

BY MR. O'CONNOR:

Q. Are you aware of any DEA guidance that's ever been issued that supports the statement you just made?

A. In regards to the -- whether

the MOAs are all legal requirements? No, sir.

Q. Okay. In connection with your opinion, you examined the suspicious order monitoring programs of seven manufacturers, correct?

A. Yes, sir.

Q. And each of those programs or systems was different from one another, correct?

A. Yes, sir.

Q. And you believe they all fell short of the regulatory responsibilities imposed by the CSA and CFR, correct?

A. Yes, sir. Just to add the caveat that some of them didn't have systems, but, yes, sir.

Q. Fair to say of the seven you saw, you weren't satisfied with any of them?

A. That's correct.

Q. Have you ever come across a manufacturer's suspicious order monitoring program that you did think satisfied regulatory requirements?

MR. FULLER: Form.

A. I can think of one.
BY MR. O'CONNOR:
Q. What was that?
A. I'm not sure I can discuss that with the Touhy letter.
MR. FULLER: Not if it was based on an investigation that you did while an agent.
MR. O'CONNOR: Sorry, are you not answering that question?
THE WITNESS: That's what I stated, sir.
MR. O'CONNOR: Okay.
THE WITNESS: Because it's not publicly readily available that someone would know that.
BY MR. O'CONNOR:
Q. While we're talking about Touhy, you have said and your counsel has stated on a number of occasions yesterday and today that you're not permitted to speak about any particular investigation you were involved in while at the DEA; is that fair?
A. That's not publicly or readily available.

Q. Okay. And with respect to Mallinckrodt in particular, given those restrictions, is it fair to say that all of the opinions you express in your report are based on materials that you reviewed in connection with this litigation?

A. Yes, sir.

Q. And your opinions are not based on any other information outside of what you've relayed and referred to in your report?

A. Well, it's difficult to -- since I worked the case for a period of years, obviously, that there may be things I know that aren't part of the discovery, but the opinion I wrote is only based on the information contained in my report.

Q. Okay. And do you intend at trial to offer any information or opinions that are based on something other than what you've cited here in this report?

MR. FULLER: Object to form, based on the same basis earlier.

A. If the Touhy letter is in place and it's restricted by the government, then I

likely than not, but it occurs more frequently now than it ever has.

Q. How much oxycodone would a pharmacy have to purchase for you to conclude that it's diverting oxycodone?

A. I'd have to see their customer file and what their scope of business, who they're supplying to be able to make that determination. There's not just a --

Q. And that's because you cannot determine whether diversion is occurring simply by looking at the volume, correct?

A. That's not correct. So if we look at a pharmacy with a population of 1,000 people and there's a million pills go there -- and that's an extreme case, but I think I could clearly say there's something occurring, diversion's occurring there.

If it's an amount that's not consumable by that geographic area, I would say it's very likely that there's diversion occurring.

Q. Outside of this extreme case that you mention where there's a population of 1,000 getting a million pills, fair to say

that a manufacturer can't tell if the diversion is occurring simply by looking at the volume of a purchase?

A. Are you saying that if they saw that situation, they would say that diversion is occurring and then outside of that situation? I think generally speaking, just looking at volume of a pharmacy, I think they would have sufficient data.

So let's say, for example, Mallinckrodt, they distribute to many distributors who then distribute to many pharmacies, so I think they have established a pretty good baseline of what a usual order is. So I think they would identify some pharmacies by volume that would rise to a level of suspicion.

I would agree -- generally agree that in most cases the amount of the drug alone wouldn't immediately make them suspicious -- say that that is a suspicious order, but I think there is a point or a volume where it's very likely that is going to occur. Florida would be an example of that.

Q. With respect to your review of manufacturers' suspicious order monitoring programs, what methodology did you apply in coming to your opinions?

A. The one that was identified or the lack of one that was identified by each manufacturer.

Q. But what methodology did you apply when assessing the suspicious order monitoring programs?

A. Well, I would apply my training, experience, knowledge in doing these kinds of cases, in regards to what I -- was provided to me to make judgment and form an opinion.

Q. And when you say "provided to," you mean by plaintiffs' counsel?

A. No, by -- in discovery.

Q. And you received that discovery -- those discovery materials through plaintiffs' counsel, correct?

A. Yes, but at my direction of what documents I wanted to see. I know we'll get back to the --

Q. So you --

A. -- the, you know, whether everything was provided to me, but my opinion is based on -- which I believe is everything that was available and the topics I requested.

Q. Okay. So your opinion is based solely on your review of the documents that you received and that -- and your experience; is that fair?

A. Experience and training, yes, sir.

Q. Okay.

A. And legal guidance.

Q. From plaintiffs' counsel?

A. No, from my employment with the DEA.

Q. So your own legal opinions?

A. No, receiving legal guidance from lawyers.

Q. Okay. At DEA?

A. Yes, sir.

Q. Okay. Are you familiar with Scott Higham?

A. The Washington Post reporter?

Q. Yes.

A. Yes, sir.
Q. Have you ever had a conversation with Scott Higham?
A. Yes, sir.
Q. How many times?
A. I don't know, four or five.
Q. What was the substance of those communications?
A. Initial were he was writing an article about the DEA and the new -- I think it was a regulation or change in the law -- change in regulation or law which was in regards to when a registrant sees some adverse or administrative action, they get to do a correction plan. And I think he wanted me to make some comments on that, so I provided some comments I believe that he published in an article.
Q. Did you ever discuss Mallinckrodt with Scott Higham?
A. I believe I probably did, postsettlement.
Q. When was your first conversation with Mr. Higham?
A. I don't recall.

investigation, whether you would raise those with the registrant?

MR. FULLER: Same objection and instruction. Point out to counsel that we have a 30(b) of the DEA on Friday and you can ask the question.

THE WITNESS: I'm not going to answer the question because of the Touhy.

BY MS. LUCAS:

Q. Well, are you aware that Mr. Prevoznik has testified that if the DEA has concerns about a registrant's suspicious order monitoring written policies, it would raise those concerns with the registrant?

A. I would -- I would either not be surprised or not surprised that he raised those concerns, but I believe he would be, in his position, in a better position to be able to know whether to release that information and the public availability. I don't. Or whether he has a Touhy authorization to speak to that or not.

Q. Well, you're not telling me that if a DEA diversion inspector came to

Janssen and inspected the system, the suspicious order monitoring system, and had concerns about that program, you're not telling me that they would just do nothing, right?

MR. FULLER: Object to form. Same Touhy issue.

A. I can't answer that because of the Touhy issue but I'm not making a comment one way or the other on that statement.

Taking the Touhy doesn't mean that I'm not answering affirmatively or negatively.

BY MS. LUCAS:

Q. Whether a suspicious order monitoring program is compliant with the CSA depends on the type of company and the scope of the business model and customers you said earlier, correct?

A. Some of the things, yes, ma'am.

Q. Would it also depend on the medications at issue? Yes or no?

A. That could have a bearing also.

Q. The abuse rates of those medications?

A. Yes, or the nonabuse rates.
Q. The geographic location or where they're being sold?
A. Yes.
Q. The sales volume in that geography?
A. That could be another factor, yes, ma'am.
Q. All right. I'm going to ask you some quick yes or nos and then I need to pass the witness while reserving my rights since I have many, many more questions for you.
Do you know how many customers Janssen had during the time it sold Duragesic?
A. No, I do not.
Q. Do you know how many customers Janssen had during the time it sold Nucynta?
A. I have not evaluated that information as far as the ARCOS, so, no, I do not at this time.
Q. Do you know how many orders per month Janssen received from its customers for Duragesic?

A. No, I do not at this time.
Q. Do you know how many orders per month Janssen received from its customers for Nucynta?
A. No, I do not, not at this time.
Q. Do you know Janssen's market share for its opioid medications sold in the Track 1 jurisdictions?
A. No, I do not at this time.
Q. Do you know the rates of diversion for Duragesic or Nucynta in the Track 1 jurisdictions?
A. I'm not sure there's any analysis or information available to give any concise rate of diversion of any drug.
Q. So is that a no?
A. I think that's a no.
Q. Do you know how many shipments of Duragesic Janssen flagged through its algorithm and investigated as potentially suspicious?
A. Janssen's never reported a suspicious order to the DEA.
Q. My question was different.
A. Oh, I'm sorry. Misunderstood

it then.

Q. Do you know how many shipments of Duragesic Janssen's algorithm flagged and Janssen subsequently investigated before releasing?

A. I do not.

Q. Do you know how many shipments of Nucynta Janssen flagged as potentially suspicious and investigated before releasing?

A. I didn't do that type of analysis up to today on that, on the data in regards to those products and that registrant.

Q. Yes or no, did you know that Janssen has reported a physician to the DEA based on a sales representative's tip?

A. I have not reviewed a document that had indicated that to me, no, ma'am.

Q. Do you know of any instance in the Track 1 jurisdictions of Duragesic being diverted?

A. At this time, no, ma'am.

Q. Do you know of any instance in the Track 1 jurisdictions of Nucynta being diverted?

A. At this time, no, ma'am.

Q. Do you know how many inspection -- or strike that.

Do you know how many regulatory investigations Janssen -- strike that again.

Do you know how many DEA regulatory investigations of Janssen distribution centers were conducted during the relevant time period in this case?

A. I do not because that information would not be available to me.

Q. Are you aware, yes or no, that the DEA conducted multiple regulatory investigations of Janssen using at least 14 different DEA diversion investigators since 2008?

A. Were those regulatory investigations that -- I'm sorry, with your question --

Q. Were you aware of --

A. Could you answer --

Q. Well, let me --

A. Could you restate that for me? Just whether it was inspections or regulatory investigations, I just need clarification.

Q. Were you aware that the DEA conducted multiple regulatory investigations of Janssen using at least 14 different DEA diversion investigators since 2008?

A. No, I'm not aware of that, but just for clarification purposes, I've been at manufacturers where there were groups of people, so the number, multiple, I would acknowledge is more than one.

But when you say 14 people, to go to a manufacturer, sometimes there are large groups of people that go, so...

Q. Is that a no?

A. It's -- so I would answer that with the information you provided me, I wouldn't comment. I don't know one way or the other.

Q. Were you aware of any regulatory investigations of Janssen by the DEA since 2008?

A. I don't have any direct knowledge of any investigations, ma'am.

Q. Did you ask to see any documents reflecting DEA regulatory investigations of Janssen?

A. I believe he did make that comment, yes. He didn't say that it was sufficient to be compliant, but he did say it was an improvement.

Q. But again, he didn't say that it wasn't compliant with DEA regulations?

A. No, I didn't say that.

Q. My question to you is: He didn't say that it wasn't compliant with DEA regulations?

A. He never made that exact statement.

Q. Teva also had an internal audit of its own suspicious order monitoring program?

A. I believe so, yes.

Q. And that program was rated overall as effective, correct?

A. Yes, but it's an internal audit.

Q. The DEA regulations don't require that companies actively audit their own programs, correct?

A. No, that's true. But I only make that statement because sometimes the

person that does the audit, without knowing the full information on the audit, is the person in charge of the system, so they don't typically give a bad audit to themselves.

So, I mean, I'm not totally discounting it, but I'm always concerned about internal audits.

Q. Mr. Rafalski, in your report you don't identify any suspicious order that Teva shipped to Summit County or Cuyahoga; isn't that correct?

A. I do not identify any single suspicious order -- any order specifically that was suspicious.

Q. And that goes for Cephalon and the Actavis entities as well, correct?

A. As I sit here today, that's an accurate statement.

Q. And you don't identify any order that Teva failed to flag as suspicious?

A. Is that question a specific order?

Q. Any order that Teva failed to flag as suspicious, you don't have an example of any specific order?

A. No, I think my examples in here are more -- go more to the conduct of the due diligence and it doesn't specifically say that there was a specific order, but I think the totality of the incident that I describe on page 183 I think would include that, but to answer your question, there's no specific order where I state that.

Q. And I want to ask you quickly about that order.

You're speaking of the Publix Supermarket pharmacies incident or scenario that we discussed -- that's in your report on page 183?

A. Yes, I am.

Q. The orders involving the Publix Supermarket pharmacies were not orders placed from Publix to Teva, were they?

A. No, they were placed to a distributor, an in-between so --

Q. Right. They were orders placed from Publix to Anda, correct?

A. Yes. But so the first concern that I would have with this is that Teva would need a means of effective controls to

go to Anda and see why this situation occurred.

Q. And it did do that, correct?

A. I don't recall that occurring.

Q. Well, so you read the deposition of Joe Tomkiewicz, didn't you?

A. Yes.

Q. And sitting here today, you don't know whether any of Teva's product was ultimately shipped to one of those Publix Supermarkets that Joe Tomkiewicz identified as entities he wanted to look into, correct?

A. Based on my review, he was looking at the chargebacks, and I believe they were Teva products.

Q. But you would agree with me that Joe Tomkiewicz testified he didn't see any specific orders of Teva's products, correct?

A. Yes, but if they weren't Teva's products, I'm not sure that he would have taken all this action unless he was indicating it was someone else's product that he was going to go investigate.

Q. Well, he could have been

Q. And so I'd like you, if you could, to just open your report to page 7. You know that Anda, Inc. is one of the defendants in this action, right?

A. I believe so, yes, sir.

Q. Okay. Looking at page 7 of your report, in the second full paragraph, you wrote: I am of the opinion to a reasonable degree of professional certainty that there was a systematic, prolonged failure over many years by the defendant manufacturers and distributors to maintain effective controls against diversion of legitimate opioid prescriptions into the illicit market.

Did I read that correctly?

A. You did.

Q. So Anda is a defendant, right?

A. Yes, sir.

Q. And that opinion as described on page 7 does not apply to Anda, right?

A. As I sit here today, no, I have not reviewed any records related to Anda.

Q. Okay. I want to ask one more question following up on your testimony.

During the course of the deposition, you've said on several occasions that your method for assessing the defendants' suspicious order monitoring systems is based in part on your experience, training and guidance from lawyers at DEA; is that correct?

Do you remember that testimony?

A. Yes, sir.

Q. Okay. This is just a yes-or-no answer: Does the Touhy authorization that you received for today's testimony prevent you from disclosing the legal guidance from DEA lawyers that supports your opinions?

A. So just so I understand the question. Does the Touhy letter prevent me from answering that question?

Q. Right.

A. I believe it does, yes.

MR. MATTHEWS: Thank you. I have no further questions.

THE VIDEOGRAPHER: Going off the record, 5:18 p.m.

(Proceedings recessed at 5:18 p.m.)